Attorney Docket No.: Q95047

REMARKS

Claim 6 has been amended to resolve an issue raised by the Examiner. Entry of the

amendment is respectfully requested.

Information Disclosure Statement

Applicants note that an Information Disclosure Statement with a Statement under 37

C.F.R. 1.97(e), the IDS fee, and a European Search Report and references is submitted herewith.

Applicants respectfully request that the Examiner consider the disclosed information and return

an initialed PTO/SB/08 form with the next communication from the PTO.

Objection to Claim 6

On page 2 of the Office Action, the Examiner has objected to claim 6 because the word

"compound" should be deleted in the second line, as the corresponding word has been deleted

from base claim 1.

In response, Applicants have deleted the word "compound" from the second line in claim

6. Accordingly, Applicants submit that this objection has been overcome, and withdrawal of the

objection is respectfully requested.

Obviousness Rejections

On page 3 of the Office Action, claims 1-4 and 8-10 stand rejected under 35 U.S.C. §

103(a) as being unpatentable over Nishikawa et al (Materials Sci. and Eng. C8-9: 495-500;

1999), in view of Watanabe et al (Biomacromolecules 3: 1109-1114; 2002), and further in view

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AMENDMENT UNDER 37 C.F.R. § 1.116

Application No.: 10/580,029

Attorney Docket No.: Q95047

of Sawhney, A. (U.S. Patent No. 6,818,018; filed August 14, 1998). Also, on page 3 of the Office Action, claims 1 and 6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nishikawa et al, in view of Watanabe et al, and further in view of Sawhney, A., as applied to claims 1-4 and 9-10 above, and further in view of Zou et al (U.S. Patent Publication No. 2002/0187105; filed February 1, 2002).

In response, Applicants maintain that the present invention is not obvious for the reasons of record, and rebut the Examiner's several counterarguments as follows.

(a) The Examiner indicates that it is unclear how amphiphilic polymers are excluded from the instant claims and that the polylactic polymer contains polar water soluble groups, as lactic acid is water soluble.

Applicants would like to bring to the Examiner's attention the fact that the water soluble groups in a lactic acid molecule disappear as a result of its polymerization. Namely, a carboxy group (-COOH) and a hydroxy group (-OH), which are water soluble groups, form a carboxylic acid ester group (-COO-), which is not water soluble. After polymerization, there remain no polar water soluble groups in the polymer except at both ends. Applicants submit that an ordinary artisan would not recognize polylactic acid as an amphiphilic polymer even though it has polar water soluble groups at both ends, since the polymer is almost entirely hydrophobic. As to a phospholipid, it contains a water insoluble carbon chain lipid and also polar water soluble groups. However, since it is not covalently bonded to a polylactic acid polymer according to the present invention, the phospholipid does not render the polylactic acid polymer of the present invention amphiphilic. Therefore, amphiphilic polymers are excluded from the instant claims.

(b) The Examiner also indicates that Applicants' assertion in the previous Remarks is in conflict with the teachings of Applicants' own specification.

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It is true that a phospholipid can be used to control contact angle of the honeycomb

structure film by adjusting its concentration according to the present invention. However, this is

but one aspect of the contribution of the phospholipid to the present invention, and it is not the

only reason for using the phospholipid. Using the phospholipid is crucial for preparing the

honeycomb structure in the first place. Applicants submit that the Examiner has improperly

utilized teachings of the instant Specification to prepare the present obviousness rejection.

To support this argument further, Applicants submit herewith a copy of the relevant

portion of a Japanese textbook "Specialty Polymer" and its English translation. In particular,

please refer to the article "2.5.3 Preparation of honeycomb film from polymer other than

amphiphilic polymer", which indicates that even when a chloroform solution of polylactic acid

falls in drops to a water surface and high humidity air is blown on the droplets formed, a porous

structure is not formed (see Fig. 13, the middle position, left).

Therefore, Applicants submit that it was common knowledge for an ordinary artisan that

a honeycomb structure could never be prepared from polylactic acid without adding an

amphiphilic polymer before the present invention was made.

Thus, Applicants submit that the present invention is not obvious over the cited art

combinations, and withdrawal of these rejections is respectfully requested.

Provisional Obviousness-Type Double Patenting Rejection

On page 5 of the Office Action, claim 1-4 and 6 stand provisionally rejected under the

judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 4-10 and 12 of copending U.S. Patent Application No. 10/552,685 (Patent Publication No.

2006/0189911; commonly assigned).

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AMENDMENT UNDER 37 C.F.R. § 1.116

Application No.: 10/580,029

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In response, and to expedite allowance, Applicants submit herewith a terminal

disclaimer to obviate this provisional rejection. Accordingly, Applicants submit that this

provisional rejection has been overcome, and withdrawal of this provisional rejection is

respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is

kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

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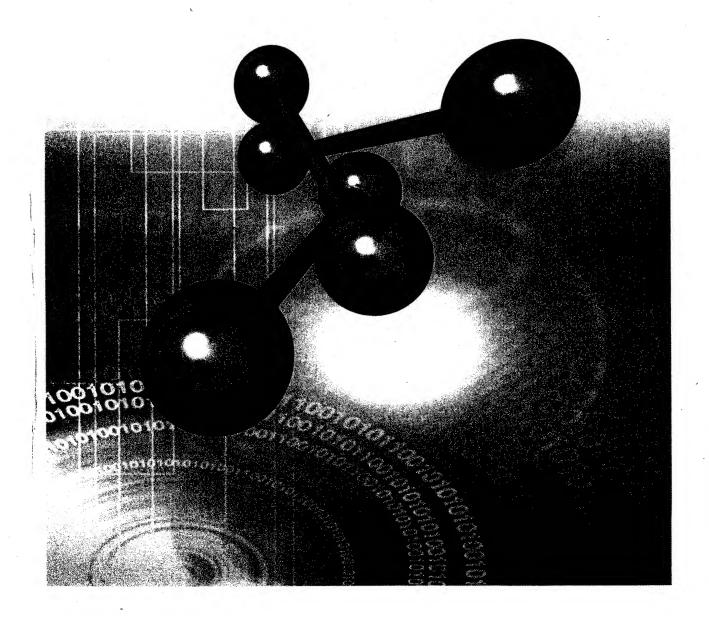
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スペシャリティポリマー

―要求特性を満たすナノレベルの材料設計―



(社)高分子学会編 THE SOCIETY OF POLYMER SCIENCE, JAPAN



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5

多孔性高分子薄膜の作製と応用展開

理化学研究所フロンティア研究システム散逸階層構造研究チーム 西川 雄大

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粘接着剤の高機能化・多機能化

古河電気工業(株) 環境・エネルギー研究所ナノテクセンター 主席研究員/チーム長 加納 義久

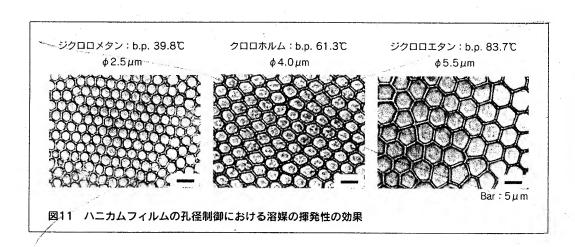
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		6 傾斜ドメイン構造の形成因子		
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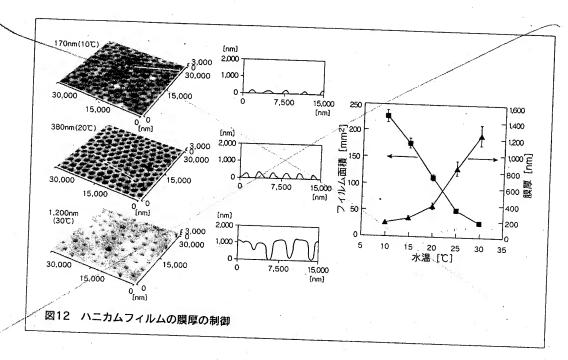
はハニカム構造の鋳型となる水滴の形成およびその安定化とフィルム構造を作る役割を担っています。両親媒性高分子の濃度を上げることで界面活性能が高まるので、水滴ができやすくなり、孔径は小さくなる傾向を示します。ポリマー濃度が低くなると、孔径が大きくなるとともに、構造が不均一になります。特に、膜厚の不均一化が生じます(図 10 左側参照)。先ほど、ポリマー溶液のキャスト量を変えることで孔径の制御を行ないましたが、ポリマー溶液の蒸発時間は使用する溶媒の蒸発性によっても制御可能です。それを示したのが図 11 です。ポリマー溶液の調製に用いた溶媒はジクロロメタン、クロロホルム、ジクロロエタンの三種類で、この順番に蒸発が遅くなっていきます。蒸発が遅くなることで、水滴の成長に要する時間が長くなり、孔径が大きくなる傾向にあります。

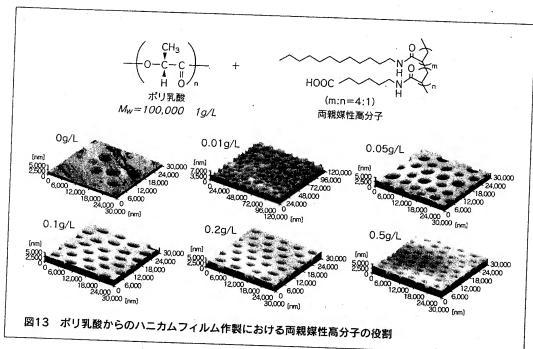
ハニカムフィルムのもう一つの構造パラメータはフィルムの厚みです。前述のようにハニカムフィルムを水面上で作製することの利点として、ポリマー溶液を滴下する水面の温度を制御できることが挙げられます。水面に滴下されたポリマー溶液は液滴を形成しますが、この拡がりは水の表面張力により影響を受けます。そこで、水温を 10、20、30 ℃と変化させてハニカムフィルムを作製し、そのときの膜厚を調べてみました(図 12 参照)。その結果、水温が低いほど膜厚が薄くなる傾向を示しました。水温が低いほど水の表面張力が高くなるので、液滴の拡がりが大きくなるからです。一方、水温が高くなると、液滴の拡がりが抑えられ、厚みを持ったフィルムが得られます。さらに、水温が 30 ℃以上になると、孔の配列の規則性が失われる結果が得られました(図 12 左下参照)。

2.5.3 両親媒性高分子以外の高分子からのハニカムフィルム作製

次に、両親媒性高分子以外の一般的な高分子からハニカムフィルムを作製するときの構造制御について述べます。図 13 では、分解性・生体吸収性高分子であるポリ乳酸を用いたハニ



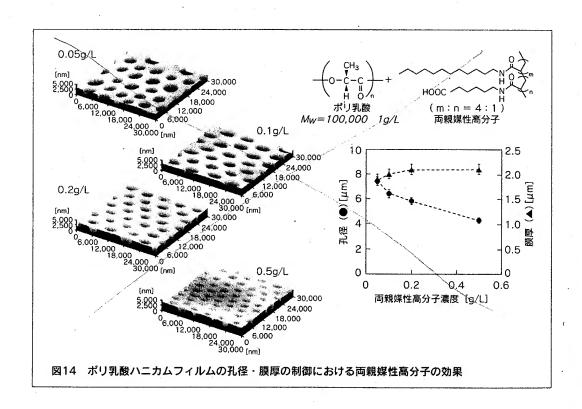


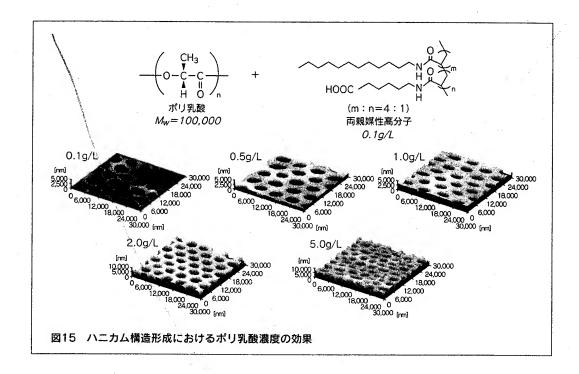


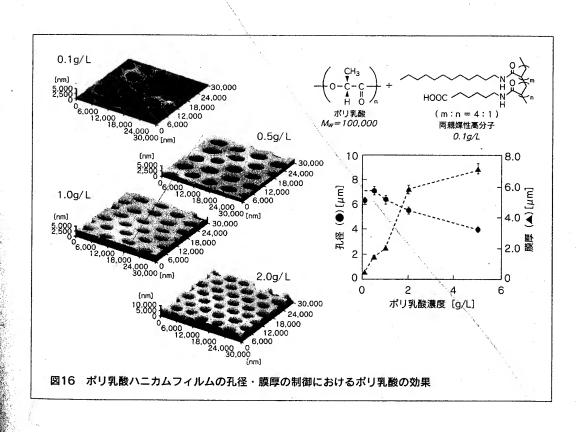
カムフィルム作製をまとめました。先ほども少しふれましたが、両親媒性高分子以外の高分子からハニカムフィルムを作製するには少し工夫が必要になります。たとえば、ポリ乳酸のクロロホルム溶液を水面上に滴下して形成した液滴に高湿度空気を吹き付けても、ポーラスな構造

体はできません (図 13 中段左参照)。そこで、ポリ乳酸以外に両親媒性高分子を共存させてフィルム作製を行ないます。ポリ乳酸に対して両親媒性高分子を重量比で数 %加えることで、ハニカム構造が形成されることがわかりました (図 13 中、下段参照)。ポリ乳酸の濃度が 1g/Lである場合、両親媒性高分子の濃度を 0.05 g/L以上にすると安定にハニカムフィルムが得られました。この結果からも、ハニカム構造形成において鋳型となる微小水滴の形成が鍵を握っていることがわかります。

構造制御のところでも述べましたが、ポリ乳酸ハニカムフィルムの場合も、両親媒性高分子の濃度を変化させることによって孔径をコントロールできるのです。これを図 14 に示しました。この場合、ポリ乳酸の濃度を一定、両親媒性高分子の濃度を変化させています。その結果、フィルムの厚みは $2\,\mu$ m でほぼ一定になるのですが、孔径は両親媒性高分子の濃度の上昇に伴い、 $7\,\mu$ m から $4\,\mu$ m に減少します。ポリ乳酸を用いてハニカムフィルムを作製する場合、両親媒性高分子が不可欠であることを述べましたが、先ほどとは逆に一定濃度の両親媒性高分子に対してポリ乳酸の濃度を変えていく場合、ハニカムフィルムの構造にどのような変化が現れるのでしょうか?図 15、16 によると、ポリ乳酸の濃度が低い場合、膜厚が不均一になります。ポリ乳酸の濃度が高くなるにつれて、膜厚が増加し、孔径の減少が見られます。この場合、孔径の減少よりも膜厚の増加が顕著であることが特徴的です。また、ポリ乳酸の濃度が高







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。 すま(も)ノ示表コスーヤ計画宝

- 本域・順巾

Polymer Frontier 21 Series 17

SPECIALTY POLYMER

Material design in nanolevel satisfying requirement characteristics

THE SOCIETY OF POLYMER SCIENCE, JAPAN

5. Preparation of porous polymer membrane and application development

RIKEN, Japan, Frontier Research System, Dissipation
Hierarchical Structure Research Team

Yudai Nishikawa 1. Formation mechanism of honeycomb film 113 2. Porous polymer membrane 113 2.1 Preparation of porous polymer film 113 2.2 Research relating to honeycomb film 114 2.2.1 Finding of honeycomb film 114 2.2.2 Other study examples 115 2.3 Formation mechanism of honeycomb film 116 2.4 Honeycomb film and polymer 118 2.5 Structure control of honeycomb film 118 2.5.1 Film preparation method 118 2.5.2 Structure control of honeycomb film 120 2.5.3 Preparation of honeycomb film from polymer other than amphiphilic polymer 122 2.5.4 Shape control of pore by stretching 127 2.6 Introduction of ligand molecule into honeycomb film 128 3. Development of honeycomb film to biological tissue engineering 131 3.1 Biointerface in biological tissue engineering 131 3.1.1 Study example of micropatterned cell culture

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2.5.3 Preparation of honeycomb film from polymer other than amphiphilic polymer

Structure control when a honeycomb film is prepared from a general polymer other than an amphiphilic polymer is described below. The preparation of a honeycomb film using polylactic acid which is a degradable and bioabsorbable polymer is summarized in Fig. 13. As previously mentioned, some creative thinking is necessary to prepare a honeycomb film from a polymer other than an amphiphilic polymer. For example, even through a chloroform solution of polylactic acid is fallen in drops to a water surface and high humidity air is blown to the droplets formed, porous structure is not formed (see Fig. 13, the middle position, left). Therefore, film preparation is conducted in the presence of an amphiphilic polymer in addition to the polylactic acid. It is understood that a honeycomb structure is formed by adding the amphiphilic polymer in an amount of several % in weight ratio to the polylactic acid (see Fig. 13, the lower position). In the case that the concentration of the polylactic acid is 1 g/liter, a honeycomb film was stably obtained when the concentration of the amphiphilic polymer is 0.05 g/liter or more. It is understood from this result that formation of fine droplets becoming template holds the key in the formation of a honeycomb structure.

Polylactic acid Amphiphilic polymer

Fig. 13 Role of amphiphilic polymer in preparation of honeycomb film from polylactic acid

Polymer Frontier 21 Series 17

SPECIALTY POLYMER

Material design in nanolevel satisfying requirement

characteristics

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